Table 1.--Record and Reporting Requirements by Product

| Products | Manufacturer | | | | | | Dealer/ Distributor |
|---|---|---|---|---|---|---|---|
| | Product reports §1002.10 | Supplemental reports §1002.11 | Abbreviated reports §1002.12 | Annual reports §1002.13 | Test records §1002.30(a) [1] | Distribution records §1002.30(b) [2] | Distribution records §1002.40,.41 |
| **DIAGNOSTIC X RAY [3] (§§1020.30—1020.33)** | | | | | | | |
| Computed Tomography | X | X | | X | X | X | X |
| X-ray System [4] | X | X | | X | X | X | X |
| Tube Housing Assembly | X | X | | X | X | X | |
| X-ray Control | X | X | | X | X | X | X |
| X-ray High Voltage Generator | X | X | | X | X | X | X |
| X-ray Table or Cradle | | | X | | X | X | X |
| X-ray Film Changer | | | X | | X | X | |
| Vertical Cassette Holders Mounted in a Fixed Location and Cassette Holders with Front Panels | | | X | | X | X | X |
| Beam-limiting Devices | X | X | | X | X | X | X |
| Spot-film Devices and Image Intensifiers Manufactured After April 26, 1977 | X | X | | X | X | X | X |
| Cephalometric Devices Manufactured After February 25, 1978 | | | X | | X | X | |
| Image Receptor Support Devices for Mammographic X-ray Systems Manufactured After September 5, 1978 | | | X | | X | X | X |
| **CABINET X RAY (§1020.40)** | | | | | | | |
| Baggage Inspection | X | X | | X | X | X | X |
| Other | X | X | | X | X | X | |
| **PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET X RAY** | | | | | | | |
| Medical | | | X | X | X | X | |
| Analytical | | | X | X | X | X | |
| Industrial | | | X | X | X | X | |
| **TELEVISION PRODUCTS (§1020.10)** | | | | | | | |
| <25 kilovolts (kV) and <0.1 milliroentgen per hr (mR/hr) IRLC [5] [6] | | | X | X [6] | | | |
| ≥25 kV and <0.1 mR/hr IRLC [5] | X | X | | X | | | |
| ≥0.1 mR/hr IRLC [5] | X | X | | X | X | X | |
| **MICROWAVE/RF** | | | | | | | |
| MW Ovens (§1030.10) | X | X | | X | X | X | |
| MW Diathermy | | | X | | | | |
| MW Heating, Drying, Security Systems | | | X | | | | |
| RF Sealers, Electromagnetic Induction and Heating Equipment, Dielectric Heaters (2-500 megahertz) | | | X | | | | |
| **OPTICAL** | | | | | | | |
| Phototherapy Products | X | X | | | | | |
| Laser Products (§§1040.10,1040.11) | | | | | | | |
| Class I Lasers and Products Containing such Lasers [7] | X | | | X | X | | |
| Class I Laser Products Containing Class IIa,II,IIIa Lasers [7] | X | | | X | X | X | |
| Class IIa,II,IIIa Lasers and Products other than Class I Products Containing such Lasers [7] | X | X | | X | X | X | X |
| Class IIIb & IV Lasers and Products Containing such Lasers [7] | X | X | | X | X | X | X |
| Sunlamp Products (§1040.20) | | | | | | | |
| Lamps Only | X | | | | | | |
| Sunlamp Products | X | X | | X | X | X | X |
| Mercury Vapor Lamps (§1040.30) | | | | | | | |
| T Lamps | X | X | | X | | | |
| R Lamps | | | X | | | | |
| **ACOUSTIC** | | | | | | | |
| Ultrasonic Therapy (§1050.10) | X | X | | X | X | X | X |
| Diagnostic Ultrasound | | | X | | | | |
| Medical Ultrasound other than Therapy or Diagnostic | X | X | | | | | |
| Non-medical Ultrasound | | | X | | | | |

[1] However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.

[2] The requirement includes §§1002.31 and 1002.42, if applicable.

[3] Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see §21 CFR 1020.30(d)(1) through (d)(3).

[4] Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in §21 CFR 1020.30(c).

[5] Determined using the Isoexposure Rate Limit Curve (IRLC) under Phase III test conditions (§1020.10(c)(3)(iii)).

[6] Annual Report is for production status information only.

[7] Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.

Revision: 951011 10/11/95